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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/539,188	06/16/2005	Nobuhiro Ito	14633.8USWO	2230
52835 7590 10/10/2008 HAMRE, SCHUMANN, MUELLER & LARSON, P.C. P.O. BOX 2902			EXAMINER	
			NWAONICHA, CHUKWUMA O	
MINNEAPOLIS, MN 55402-0902			ART UNIT	PAPER NUMBER
			1621	
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			10/10/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

	Application No.	Applicant(s)				
	10/539,188	ITO ET AL.				
Office Action Summary	Examiner	Art Unit				
	CHUKWUMA O. NWAONICHA	1621				
The MAILING DATE of this communication app Period for Reply	ears on the cover sheet with the c	orrespondence address				
• •	VIC CET TO EVOIDE AMONTHU	C) OD TUUDTY (20) DAVC				
A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DA  - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period w  - Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be time will apply and will expire SIX (6) MONTHS from cause the application to become ABANDONE	lely filed the mailing date of this communication. (35 U.S.C. § 133).				
Status						
1)⊠ Responsive to communication(s) filed on <u>19 Ju</u>	ne 2008.					
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3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is						
closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.						
Disposition of Claims						
• 4)⊠ Claim(s) <u>1-3 and 5-13</u> is/are pending in the application.						
4a) Of the above claim(s) is/are withdrawn from consideration.						
5) Claim(s) 12 is/are allowed.						
6)⊠ Claim(s) <u>1-3,5-10 and 13</u> is/are rejected.						
7)⊠ Claim(s) <u>11</u> is/are objected to.						
8) Claim(s) are subject to restriction and/or	election requirement.					
Application Papers						
9) The specification is objected to by the Examine	•					
10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.						
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).						
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).						
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.						
Priority under 35 U.S.C. § 119						
12)⊠ Acknowledgment is made of a claim for foreign	priority under 35 U.S.C. § 119(a)	-(d) or (f)				
a)⊠ All b)□ Some * c)□ None of:						
1. Certified copies of the priority documents have been received.						
2. Certified copies of the priority documents have been received in Application No						
3. Copies of the certified copies of the priority documents have been received in this National Stage						
application from the International Bureau (PCT Rule 17.2(a)).						
* See the attached detailed Office action for a list of the certified copies not received.						
Attachment(s)						
Attachment(s)  1) Notice of References Cited (PTO-892)	4) Interview Summary	(PTO-413)				
2) Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Da	ite				
3) Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 05/15/2008.	5)  Notice of Informal P 6) Other:	atent Application				

#### **DETAILED ACTION**

#### **Current Status**

- 1. This action is responsive to Applicants' amendment of 19 June 2008.
- 2. Receipt and entry of Applicants' amendment is acknowledged.
- 3. Claims 1-3 and 5-13 are pending in the application.

The objection of claim 11 is maintained for the reason stated in the previous Office Action dated 02/19/2008.

The allowability of claim 12 is maintained for the reason stated in the previous Office Action dated 02/19/2008.

The 102 rejections are withdrawn following Applicants amendments. Applicants have amended the claims to over come the 102 rejections.

The 103 rejection of claims 1-10 under 35 U.S.C. 103(a) as being unpatentable over Dingwen et al., {JP 4517402} in view of Kato et al., {US 4,874,890} is maintained for the reason stated in the previous Office Action dated 02/19/2008. Applicants' arguments filed 19 June 2008 have been fully considered but they are not persuasive because Applicants claimed process is obvious in view Dingwen et al. and Kato et al. because all the claimed elements were known in the prior arts and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention.

Applicants argue that the prior art of Dingwen et al. reaction is carried out under a severe condition, i.e., a basic condition with  $D_2O_2$ , that under such severe conditions,

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the substrate compound would be decomposed, and removing such decomposed materials requires a complicated purification process. Applicants further argue that in contrast; claim I do not require the alkaline metal deuteroxide or  $D_2O_2$ , and that the process is conduced under a neutral condition using a deuterated solvent as a source of heavy hydxogen.

Applicants' arguments are not persuasive because merely modifying the process conditions such as concentration is not a patentable modification absent a showing of criticality. In re Aller, 220 F.2d 454, 105 U. S. P. Q. 233 (C. C. P. A. 1955). Applicants' arguments are based on the fact that Applicants varied the pH of the reaction medium from basic to neutral condition. The varying the reaction conditions in a chemical reaction is a well-known chemical practice to optimize the process efficiency of the system and does not constitute a patentable distinction. On of ordinary skill in the art would be able to co-relate the teaching of Dingwen et al. and Kato et al. by varying the reaction medium from basic to neutral condition to obtain an optimum reaction condition. Additionally, Applicants failed to provide a side-by-side comparison of their process and the process of the prior arts of Dingwen et al. and Kato et al. The examiner is respectfully requesting that Applicants provide a data of a side-by-side comparison to show an unexpected result or superior performance of Applicants process as opposed to the processes of Dingwen et al. and Kato et al. The submission of this data would make Applicants' argument convincing.

In addition, Applicants argue that the process of claim I effectively can deuterate a substrate compound that has a carbon- carbon double or triple bond such as

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methacrylic acid because the catalyst is activated before the detretation reaction and the compound such as methacrylic acid does not contact and accordingly, react with  $H_2$  or  $D_2$  gas that is used for activation of the catalyst.

Applicants' arguments are not persuasive because Applicants do not provide a data of a side-by-side comparison of Applicants process and the process of the prior arts. The submission of this data would make Applicants' argument convincing.

Applicants' argument that Kato et al. disclose the use of  $D_2$  gas for direct substitution process is not a valid organic chemistry argument because Kato et al. teach a process that employed a heavy hydrogen gas or heavy hydrogen solvent. One of ordinary skill in the art would be able to follow the prior arts teaching to arrive at Applicants claimed invention.

## Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

- 1. Determining the scope and contents of the prior art.
- 2. Ascertaining the differences between the prior art and the claims at issue.
- 3. Resolving the level of ordinary skill in the pertinent art.

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4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-10 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dingwen et al., {JP 4517402} in view of Kato et al., {US 4,874,890}.

Applicants claim a method for deuteration of a compound represented by the general formula 1; wherein all the variables are as defined in the claims.

## <u>Determination of the scope and content of the prior art (M.P.E.P. §2141.01)</u>

Dingwen et al. teach a general method that enables the replacement of light hydrogen with a heavy hydrogen isotope in numerous organic compounds including high molecular weight compounds. This new method can be used to manufacture heavy hydrogen containing compounds on a small scale experimentally and, moreover, it can be used for manufacturing on an industrial scale.

Dingwen et al. teach that the immediate substitution of light hydrogen with deuterium is possible using appropriate sources of heavy hydrogen (deuterium). In the initial attempts at substituting light hydrogen with deuterium, organic compounds were treated with heavy water in the presence of an alkali and platinum catalyst. This method achieved the replacement of mobile hydrogen atoms. The method is characterized in that, in the course of a direct substitution reaction that occurs between an organic compound that contains light hydrogen and a source of heavy hydrogen, such as deuterium oxide, in the presence of an alkaline metal deuteroxide and a reduced Adams catalyst ( $PtO_2 \cdot H_2O$ ), deuterium peroxide is added as the reaction promoter.

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The method can be used to manufacture, for example, a completely deuterated aliphatic acid, dicarboxylic acid, ketone, alcohol, and a variety of hydrocarbons; therefore, it has broad applicability. This method can be used to produce deuterium-containing compounds with a high degree of isotope purity (99% or more), and this degree of isotope purity is limited only by the degree of isotope purity of the deuterium source.

# Ascertainment of the difference between the prior art and the claims (M.P.E.P.. §2141.02)

Dingwen et al. method for deuteration of a compound differs from the instantly claimed process in that applicants' claim a process that employs a hydrogen gas or heavy hydrogen gas while Dingwen et al. are silent about the use of a hydrogen gas or heavy hydrogen gas.

However, Kato et al. teach a process that employed a heavy hydrogen gas. See page 476.

# <u>Finding of prima facie obviousness--rational and motivation (M.P.E.P.. §2142-2143)</u>

The instantly claimed method for deuteration of a compound would have been suggested to one of ordinary skill because one of ordinary skill wishing to obtain a deuterated compound is taught to employ the processes of Dingwen et al. and Kato et al.

One of ordinary skill in the art would have a reasonable expectation of success in practicing the instant invention by varying the process conditions from the teaching of

Dingwen et al. and Kato et al. to arrive at the instantly claimed method for deuteration of a compound. Said person would have been motivated to practice the teaching of the references cited because they demonstrate that deuterated compound are useful in industrial applications.

The Examiner notes that varying the reaction conditions in a chemical reaction is a well-known chemical practice to optimize the process efficiency of the system and does not constitute a patentable distinction. Merely modifying the process conditions such as temperature and concentration is not a patentable modification absent a showing of criticality. <u>In re Aller</u>, 220 F.2d 454, 105 U. S. P. Q. 233 (C. C. P. A. 1955).

Moreover, all the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention.

### Allowable Subject Matter

Claim 11 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chukwuma O. Nwaonicha whose telephone number is 571-272-2908. The examiner can normally be reached on Monday thru Friday, 8:30am to 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Daniel Sullivan can be reached on 571-272-0779. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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/Karl J. Puttlitz/ Primary Examiner, Art Unit 1621